

10



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,434	09/19/2001	Seang Yiv	12152.48US11	3245
23552	7590	10/05/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/957,434

Applicant(s)

YIV ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75-96 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 76-81 and 84-96 is/are allowed.
- 6) ☐ Claim(s) 75, 82, 83 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 06/15/05.

The amendment filed 06/15/04 affects the application, 09/957,434 as follows:

1. Claim 1-74 has been canceled. New Claims 75-96 have been added. This leaves claims 75-96.
2. Applicant responds to the rejection under 35 USC 103 by canceling claims 1-74 and adding claims 75-96.

The responsive to applicants' arguments is contained herein below.

Claims 75-96 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrases "wherein the surfactant comprises one or more phospholipids" and "wherein the surfactant comprises a block copolymer of ...". However, the claim is indefinite because it is unclear which of the two compounds the surfactant actually comprises. More specifically, the phrase renders the claim as being indefinite and, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

Art Unit: 1623

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nath (IN 93772) in view of Fost et al. (US 5,215,976).

In claim 82, applicants claim, "A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein the oil-in-water microemulsion comprises; a lipid, one or more pharmaceutically acceptable surfactants, one or more pharmaceutically acceptable humectants; water and one or more preservatives selected from the group consisting of sodium benzoate, methyl parabens, propyl parabens, thimerisal, and sorbic acid." Claim 83 is drawn to the composition of claim 82, wherein the preservative is sodium benzoate.

Nath discloses a spermicidal composition of an oil-in-water emulsion, wherein the oil-in-water emulsion comprises a surfactant (a glycol ester of stearic acid), alkylphenoxypoly (ethylenoxy) ethanol, stearic acid, glycerol and water. (see abstract). In addition, Nath discloses a spermicidal composition which is in a gel form, and which comprises a humectant (polyethylene glycol), a hydrogel (sodium carboxymethylated cellulose or Na CM-cellulose), alkylphenoxypoly (ethylenoxy) ethanol, and water (see abstract).

Fost et al. disclose that phospholipids can be used in spermicidal compositions (see abstract and col. 1, lines 23-53).

Art Unit: 1623

The difference between applicants' claimed composition and the composition of Nath is that applicant's composition contains a combination of the ingredients found in Nath's two compositions (surfactant, humectant, water and polymeric hydrogel) in addition to a lipid and a preservative. However, Fost et al. disclose that phospholipids can be used in spermicidal compositions and has spermicidal activity, and it is common and obvious to use preservatives in consumer pharmaceuticals such as a spermicidal compositions. It should also be noted that sodium benzoate is a commonly used preservative for pharmaceutical compositions.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Nath and Fost et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and to include any phospholipid like the phospholipid disclosed Fost et al. and a commonly used preservative such as sodium benzoate, since the combination of compounds that are used for the same purpose (e.g. as spermicidals) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Nath and Fost et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and to include any phospholipid like the phospholipid disclosed Fost et al. and a commonly used preservative such as sodium benzoate, since the combination of compounds that are used for the same purpose (e.g. as spermicidals) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 76-81 and 84-96 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record provided that they are rewritten in an acceptable independent form or they are not dependent on a rejected claim and that no new subject matter is added to these claims. The present invention relates to a spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein the oil-in-water microemulsion comprises a lipid, one or more pharmaceutically acceptable surfactants, one or more pharmaceutically acceptable humectants and water. The very relevant prior art documents (Nath, (IN 93772)) to this invention disclose a spermicidal composition including an oil-in-water emulsion.

However, though compositions of prior art documents are similar to those of the instant invention, the compositions of claims 76-81 and 84-96 of the instant invention, which are characterized by further limitations, possess ingredients or components that are different and unobvious to those of the prior art.

Response to Amendment

The applicant argues that claims 59-61, as amended herein are directed to a process of using the product of claims 1-52; and claims 53-58 are directed to a process of making the product of claim 1; and therefore should be rejoined once the subject matter of claims 1-52 is found allowable. However, claims 1-74 are cancelled and new claims 75-96 are pending in the application. Furthermore, claim 75, for example, does not correspond to any of the original claims.

Art Unit: 1623

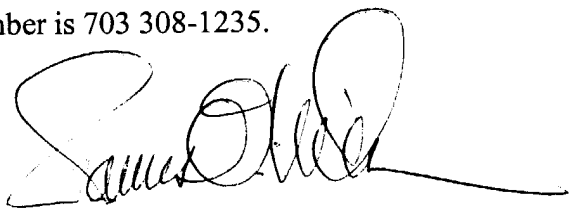
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

October 1, 2004.



JAMES O. WILSON
SUPERVISOR
COMMUNICATIONS CENTER 1000